Operating Instructions

Original Operating Instructions

Biowelder® S

1000131965

SARTORIUS

Contents

1 About These Instructions 5
1.1 Validity 5
1.2 Target Groups 5
1.3 Symbols Used 6
1.3.1 Warnings in Operation Descriptions 6
1.3.2 Other Symbols Used 6

2 Safety Instructions 7
2.1 Intended Use 7
2.1.1 Modifications to the Device 7
2.1.2 Repairs and Maintenance on the Device 9
2.2 Qualifications of Personnel 9
2.3 Functionality of the Device Parts 9
2.4 Safety Information on the Device 9
2.5 Electrical Equipment 10
2.5.1 Damage to the Device's Electrical Equipment 10
2.6 Conduct in an Emergency 10
2.7 Accessories 10
2.8 Personal Protective Equipment 10
2.9 Hot Surfaces 11
2.10 Uninterrupted Power Supply (UPS) 11
2.11 Connection for External Exhaust System 11

3 Device Description 12
3.1 Device Overview 12
3.2 Rear View 13
3.3 Symbols on the Device 13

4 Operating Design 14
4.1 Operating display 14
4.2 Buttons in the Operating Display 15
4.3 Menu Structure in the "Settings" Menu 16
4.4 Settings Weld Log 18
4.5 Audit Trail Tables 19
4.5.1 Settings Audit Trail 19
4.5.2 Archive Audit Trail 20
4.6 User Management 21
4.6.1 User Selection 21
4.6.2 Update Account Details 22
4.6.3 Create User 22
4.6.4 Delete User 23
4.6.5 Update User 24
4.7 Access Management 25
4.8 Device Settings 26

5 Installation 28
5.1 Scope of Delivery 28
5.2 Selecting an Installation Site 28
5.3 Unpacking 28
5.4 Acclimatization 29

5.5 Installing Trays ... 29
5.6 Installing the Blade Cartridge ... 29

6 Commissioning ... 29
6.1 Connecting the Power Supply ... 29
6.2 Commissioning ... 29

7 Process Preparation ... 30
7.1 Login ... 30
7.2 Clean tubes ... 30
7.3 Prepare welding process ... 30

8 Operation ... 33
8.1 Welding process ... 33
8.2 Switch off the device ... 34

9 Cleaning and Maintenance ... 36
9.1 Cleaning ... 36
9.2 Cleaning the tube holder ... 36
9.2.1 Removing the Tube Holder ... 37
9.2.2 Installing the Tube Holder ... 38
9.3 Replacing Fuses ... 39
9.4 Service Cycles ... 39

10 Faults ... 40
10.1 Error Messages ... 40
10.2 Problems during Operation ... 40

11 Decommissioning ... 42
11.1 Decommissioning the Device ... 42
11.2 Dismounting Trays ... 42

12 Transport ... 42

13 Storage and Shipping ... 43
13.1 Storing ... 43
13.2 Returning the Device and Parts ... 43

14 Disposal ... 44
14.1 Decontaminating the Device ... 44
14.2 Disposing of the Device and Parts ... 44

15 Technical Data ... 45
15.1 Dimensions and Weight ... 45
15.2 Installation | Transport Conditions ... 45
15.3 Operating Conditions ... 46
15.4 Electrical Data ... 46
15.4.1 Power Supply Unit ... 46
15.4.2 In and Out Connections ... 46
15.4.3 Fume Extraction Connector ... 47
15.5 Tube Specifications ... 47
15.6 Cleaning Agent and Cleaning Method Device ... 47

16 Conformity Documents ... 47

1 About These Instructions

1.1 Validity

These instructions are part of the device; they must be read in full and stored. These instructions apply to the device in the following versions:

Device
Biowelder® S

Software	Version, at least
Biowelder® S Software	1.13.5

1.2 Target Groups

These instructions are addressed to the following target groups. The target groups must possess the specified knowledge.

Target Group	Knowledge and Qualifications
Operator	The operator is familiar with the device and the associated work processes. The operator understands the hazards which may arise when working with the device and knows how to prevent them.
Administrator	The administrator is responsible for integrating the device into the production process. The administrator ensures the reliable functioning of the system and device software.

1.3 Symbols Used

1.3.1 Warnings in Operation Descriptions

⚠ WARNING
Denotes a hazard that may result in death or serious injury if it is not avoided.

⚠ CAUTION
Denotes a hazard that may result in moderate or minor injury if it is not avoided.

NOTICE
Denotes a hazard that may result in property damage if it is not avoided.

1.3.2 Other Symbols Used

▶	Required action: Describes activities that must be carried out. The activities in the sequence must be carried out in succession.
▷	Result: Describes the result of the activities carried out.
[ ]	Refers to operating and display elements. Indicates status, warning, and error messages.

Figures in These Instructions

Depending on the device configuration, the figures depicting the device and operating display may differ slightly from the supplied device. The variants shown in these instructions are examples.

2 Safety Instructions

2.1 Intended Use

The device is intended for sterile, automated welding of TPE and PVC tubing for cell and gene therapy bioprocessing applications. This is achieved by inserting tubing of a specific diameter into the layer provided for this purpose on the left and the right and closing the tube holder using the handle. The start slider is used to trigger the welding process.

During the cycle, the pieces of tubing are cut, softened, positioned vertically, and joined together. Following a brief cooling period, the tube holder can be opened and the two pieces of tubing that have been attached to one another can be removed, along with the waste pieces of tubing. Once all pieces of tubing have been removed, the device is reset and the used blade is ejected into the container for used blades. The weld is fully automated and is released after completion of operation.

The device is intended solely for use in accordance with these instructions. Any other use is considered improper.

Operating Conditions for the Device

Do not use the device in potentially explosive environments. Only use the device indoors. Do not use the device for domestic purposes.

The device may only be used with the equipment and under the operating conditions described in the Technical Data section of these instructions.

The device is a class A product. In a domestic environment this product may cause radio interference (emission).

The device complies with Industry Canada licence-exempt RSS standard(s) and with part 15 of the FCC rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation of the device.

To maintain compliance with FCC's RF Exposure guidelines, this device should be installed and operated with minimum distance of 20 cm the radiator body.

The device complies with IMDA standards.

2.1.1 Modifications to the Device

If the device is modified, persons may be put at risk. Device-specific documents and product approvals may lose their validity.

For queries regarding modifications to the device, contact Sartorius.

Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

2.1.2 Repairs and Maintenance on the Device

Device repairs and maintenance may only be carried out by persons with specialized knowledge of the device. If the device is not repaired or maintained by a specialist, persons may be put at risk. Device-specific documents and product approvals may lose their validity.

Sartorius recommends that any repair work, even that carried out after the end of the warranty period, is carried out by Sartorius Service or after consulting with Sartorius Service.

Only the maintenance tasks described in these instructions should be carried out. For maintenance tasks that need to be carried out by Sartorius Service, contact Sartorius Service.

2.2 Qualifications of Personnel

Persons who do not possess adequate knowledge about how to use the device safely may injure themselves and other persons.

If a particular qualification is required for an activity, the target group will be specified. If no qualification is specified, the action can be performed by the "Operator" target group.

2.3 Functionality of the Device Parts

Non-functioning device parts, e.g., as a result of damage or wear, can cause malfunctions. There is a risk of injury to persons.

- ▶ If device parts are not functioning, do not use the device.
- ▶ Comply with the maintenance intervals (intervals and maintenance tasks see Chapter "9.4 Service Cycles", page 39).

2.4 Safety Information on the Device

Symbols, e.g., warnings and safety stickers, are safety information for handling the device. Missing or illegible safety information may result in this information not being observed. There is a risk of injury to persons.

- ▶ Do not conceal, remove, or modify the symbols.
- ▶ Replace the symbols if they become illegible.

2.5 Electrical Equipment

2.5.1 Damage to the Device's Electrical Equipment

Damage to the device's electrical equipment, e.g., damaged insulation, can be life-threatening. Contact with live parts represents a danger to life.

- ▶ If the electrical equipment of the device is defective, cut off the power supply and contact Sartorius Service.
- ▶ Keep live parts away from moisture. Moisture can cause short circuits.

2.6 Conduct in an Emergency

If an emergency occurs, e.g., due to malfunctions of the device or dangerous situations, persons may be injured. The device must be immediately taken out of operation:

- ▶ Disconnect the device from the power supply.
- ▶ Prevent the device from recommissioning.

2.7 Accessories

The use of unsuitable accessories can affect the functionality and operating reliability of the device and have the following consequences:

- — Risk of injury to persons
- — Damage, malfunctions, or failure of the device

- ▶ Only use accessories that have been approved by Sartorius for this device.

2.8 Personal Protective Equipment

Personal protective equipment protects against hazards arising from the device. If the personal protective equipment is missing or is unsuitable for the work processes on the device, persons may be injured.

The following personal protective equipment must be worn:

- — Protective gloves
- — Protective goggles

2.9 Hot Surfaces

The blades in the waste container may be hot. There is a danger of burns and a risk of injury.

- ▶ Avoid contact with hot blades.
- ▶ Allow the blades to cool before touching them or dispose of them in another container.
- ▶ Wear personal protective equipment.

2.10 Uninterrupted Power Supply (UPS)

There is an integrated energy store in the device so that a welding process that is underway can be completed without any interruption in the event of a power failure.

2.11 Connection for External Exhaust System

The device has a connection for an external exhaust system. This enables the smoke produced during the welding process to be removed.

- ▶ Do not exceed the permissible air flow (see Chapter “15.4.3 Fume Extraction Connector”, page 47).
- ▷ If the air flow is too high, this can affect the welding quality.

3 Device Description

3.1 Device Overview

Fig. 1: Biowelder® S front view

Pos.	Name
1	Tray
2	Tube holder
3	Tube holder handle
4	Touchscreen color display
5	Blade cartridge drawer
6	Waste blade drawer
7	Tray holder

3.2 Rear View

Fig. 2: Biowelder® S rear view

Pos.	Name
1	XLR 5-pin connection for external air filter system
2	USB-A connection
3	Ethernet connection
4	Outlet of the external air filter system
5	Connection for the power supply
6	Fuse holder
7	Main supply switch

3.3 Symbols on the Device

Symbol	Meaning
	Hot surfaces: Danger of burns if touched
	Hazards on the device: Risk of injury due to device components
	Biohazards: Risk of injury due to biological substances
	Do not sit on an unsuitable surface

4 Operating Design

4.1 Operating display

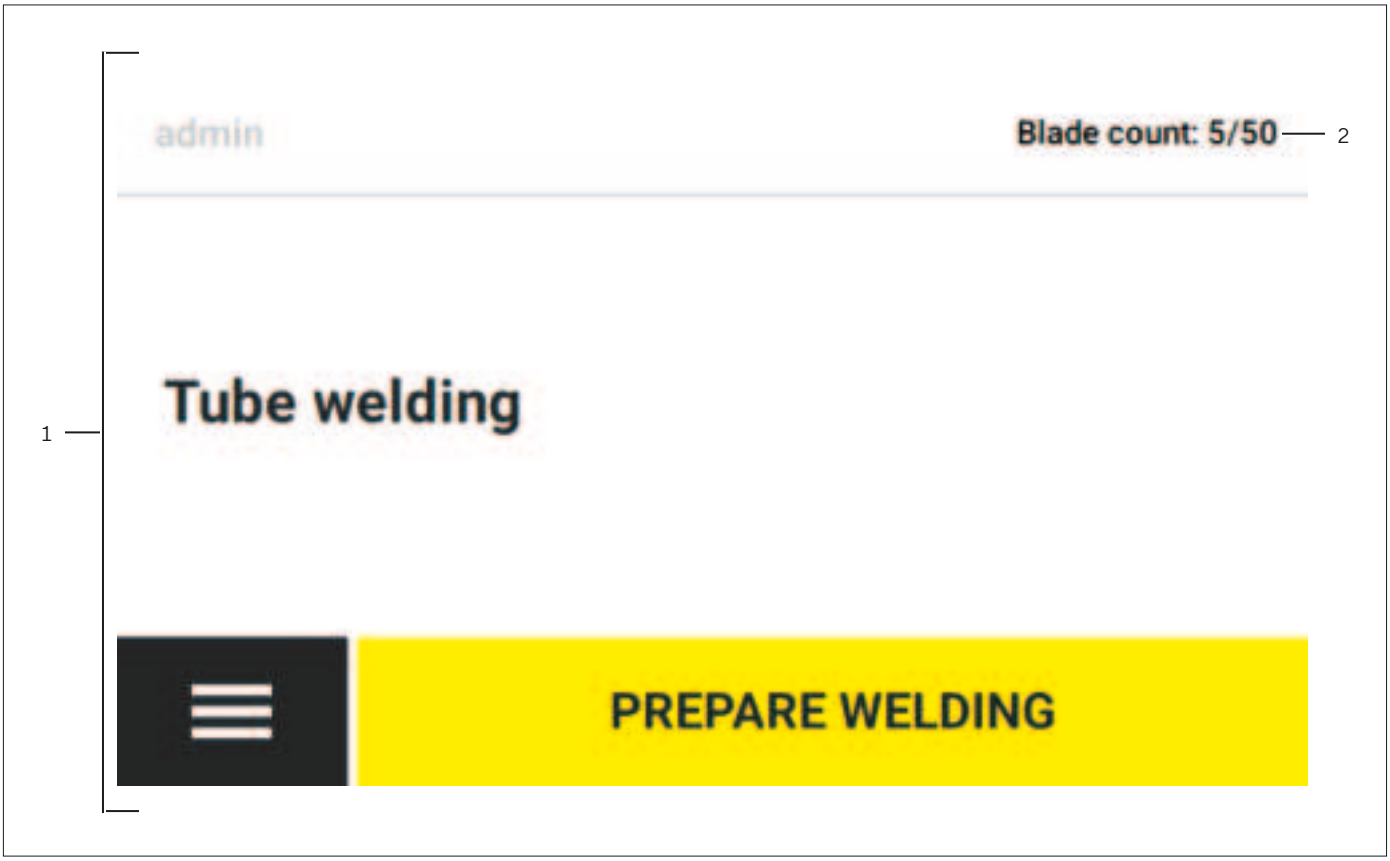
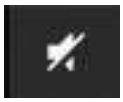
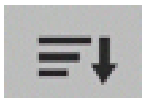


Fig. 3: Start screen

Pos.	Name	Description
1	Operating and display area	
2	Blade count display	Displays the number of available blades in the blade compartment.

4.2 Buttons in the Operating Display

Symbol	Name	Description
	[Menu] button	The settings menu opens.
	[Date | Time] button	Opens the menu to set the date and time.
	[Login] button	Opens the menu to log in as a user with password.
	[Logout] button	Logs out the current user.
	[Unmute] button	Unmutes device.
	[Mute] button	Mutes device.
	[Back] button	Returns to the previous display.
	[Confirm] button	Confirms the current input.
	[Export] button	Exports selected data..
	[Sorting] button	Sorts according to various criteria.
	[Column Selection] button	Selection of the categories to be displayed.
	[Edit] button	Edits selected category.
	[Delete] button	Deletes selected category.
	[Archive] button	Archives the data of the selected category.
	[Create] button	Creates a new item of the selected category.

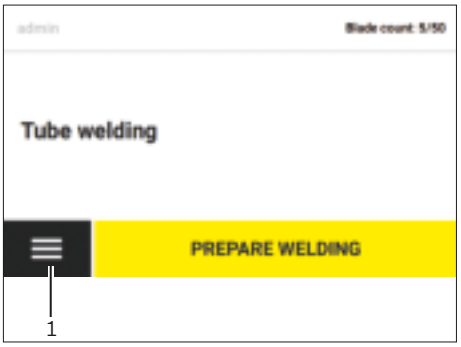
4.3 Menu Structure in the “Settings” Menu

Level 1	Level 2	Level 3	Level 4	Description
Settings	Device Information	General Device Information		Displays the general device information.
		Blade Cartridge Information		Displays information regarding the blade cartridge.
		Service Counter		Displays the remaining days and cycles until the device needs to be maintained.
		View Weld log		Displays the history of the welding operations carried out and allows users to export the weld log.
		View Audit Trail		Displays the audit trail and allows users to export it.
		Regulatory Information		Displays electronic compliance labels and information.
		Software licenses		Displays the third party software licenses used.
	User Management	User Selection		Modifies user account information.
	Access Management	Login Required		Enables | disables the necessity to be logged in for welding.
		Default Password Input		Sets the mode of the touch screen keyboard appearing when users log in.
		Auto Logout		Defines after how many minutes the user is automatically logged out.
		User Selection		Defines the maximum length of the suggested user list when logging in.
		Local User Management	Maximum Retries	Defines how often the user can repeat the password entry.
			Password Rules	Defines criteria for password use.

Level 1	Level 2	Level 3	Level 4	Description
	Device Settings	Date & Time	Date	Displays | sets the current date in the format YYYY-MM-DD.
			Time	Displays | sets the current time.
			Time Zone	Sets the current time zone.
			NTP Mode	Configures network time synchronization.
		Display Brightness	Bright	Sets the screen brightness.
			Medium	
			Eco Mode	
		Weld Settings	Tube Selection	Enables | disables the tube selection during the welding process.
			Weld Log Screen	Enables | disables the weld log screen.
			Weld Assessment	Enables | disables the weld assessment screen.
			Default Tube	Sets the default tube in the tube selection during the welding process.
		Language		Sets the language of the software.
		Network Settings	IPv4	Configures the settings for the IPv4 protocol.
			IPv6	Configures the settings for the IPv6 protocol.
			DNS	Configures the domain server settings.
		Export Settings	Export Formats	Defines export formats.
			Export Targets	Defines target storage locations for data export.
	Device Maintenance	Maintain Tube Holder		Moves the tube holder into the intended position for being removed during cleaning.

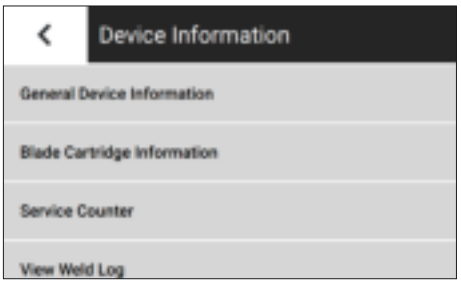
4.4 Settings Weld Log

Procedure

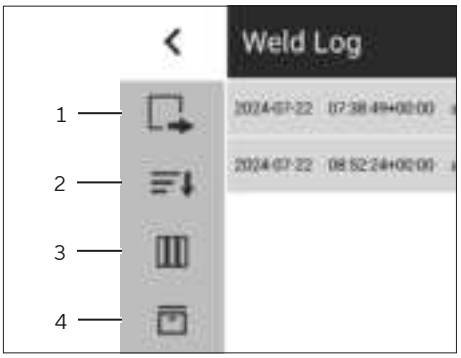


▶ Press button [Menu] (1) on the home screen.

▶ Press button [Device Information].



▶ Press button [View Weld Log].

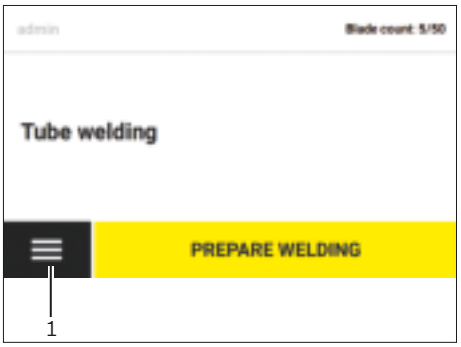


▶ Press button [Export] (1) to transfer data from the weld log.
▶ Press button [Sorting] (2) to sort the data of the weld log by selected categories.
▶ Press button [Column Selection] (3) to choose between different columns to be displayed.
▶ Press button [Archive] (4) to archive the weld log.

4.5 Audit Trail Tables

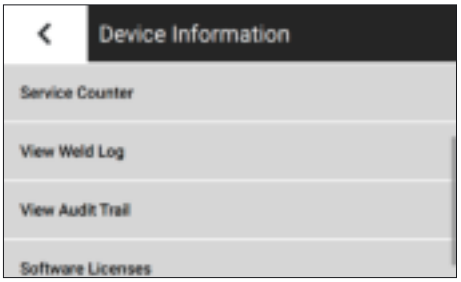
4.5.1 Settings Audit Trail

Procedure

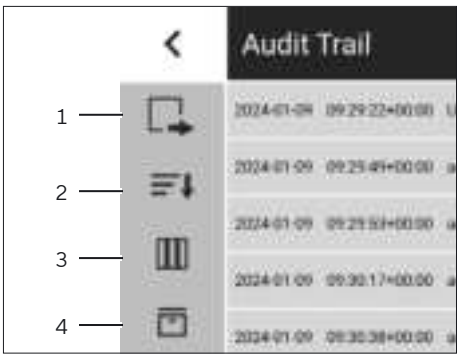


▶ Press button [Menu] (1) on the home screen.

▶ Press button [Device Information].



▶ Press button [View Audit Trail].

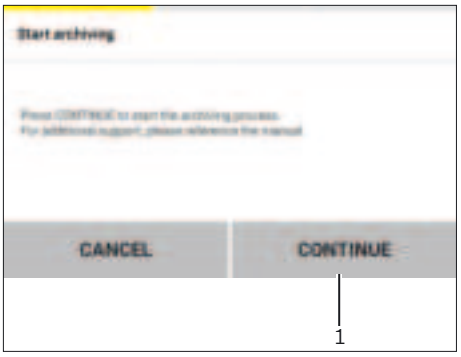


▶ Press button [Export] (1) to transfer data from the audit trail.
▶ Press button [Sorting] (2) to sort the data of the audit trail by selected categories.
▶ Press button [Column Selection] (3) to choose between different columns to be displayed.
▶ Press button [Archive] (4) to archive the audit trail.
▶ All properties that can occur in the audit trail and their description are listed in the software release notes provided with the software.

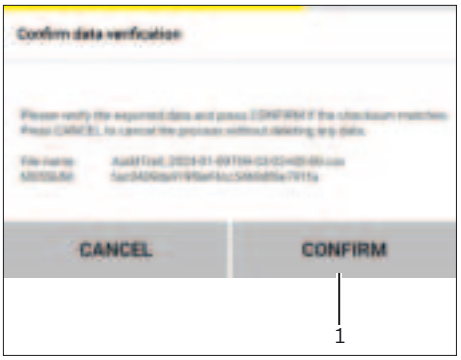
4.5.2 Archive Audit Trail

Procedure

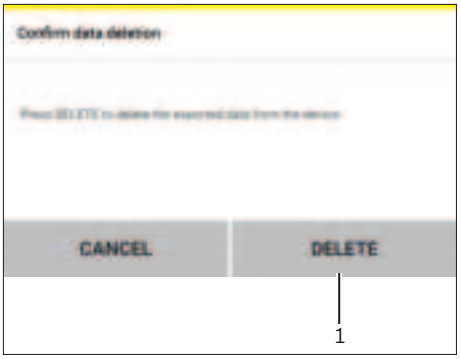
▶ Press button [Archive] (1) in the audit trail menu.



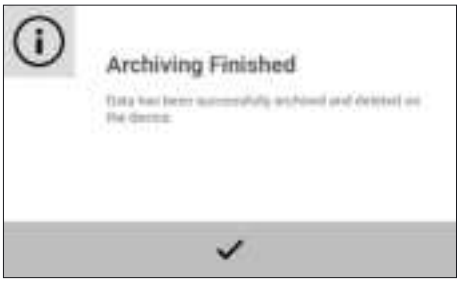
▶ Press button [CONTINUE] (1).



▶ Press button [CONFIRM] (1).



▶ Press button [DELETE] (1) to delete the exported data from the device after archiving.



▷ Archiving audit trail is finished.

4.6 User Management

4.6.1 User Selection

Procedure

▶ Press button [Menu] (1) on the home screen.

▶ Press button [User Management].

▶ Possible options:
  ▷ Operator:
  – update account details

  ▷ Administrator:
  – create user ID
  – delete user ID
  – update account details

▶ **NOTICE** All user ID's created are only visible to the administrator.
▶ Choose between already created User-ID's or add a new user ID via the button [+].

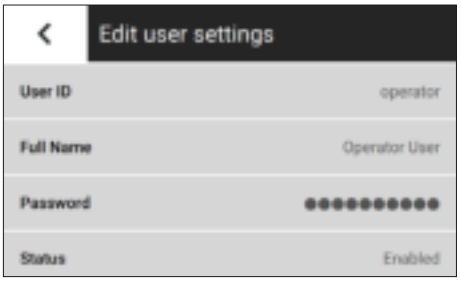
4.6.2 Update Account Details

Users with the role „Operator“ can update their account details.

Procedure

▶ Select an user account displayed.

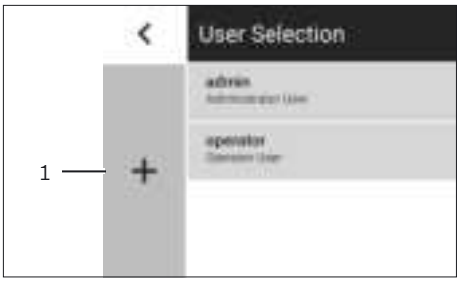
▶ Press button [Edit] (1) for further changing the details of the account.



▶ Use [Full Name] to change the full name associated with the account.
▶ Use [Password] to change the password of the account.

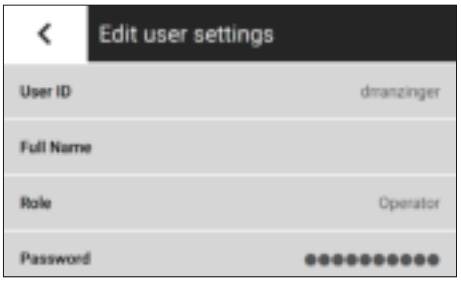
4.6.3 Create User

Procedure

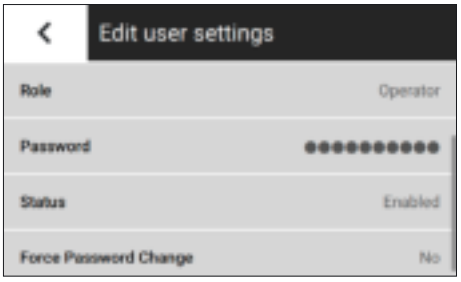


▶ Create a new user by pressing the button [Create] (1).

▶ Provide a new user ID for the new account and confirm it.



▶ Adjust [Full Name], the [Role] and the initial [Password] for the new user account as needed.



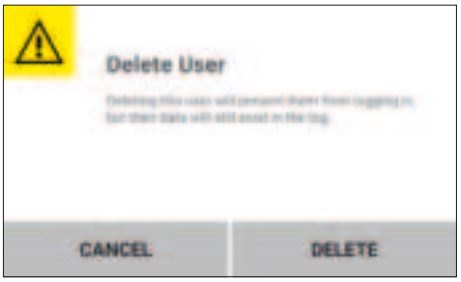
▶ Set [Force Password Change] to [Yes] if the user shall set a new password at the first login.

4.6.4 Delete User

Procedure

▶ Select the user to be deleted.

▶ Press button [Delete] (1).



▶ Press button [DELETE] to confirm the deletion.

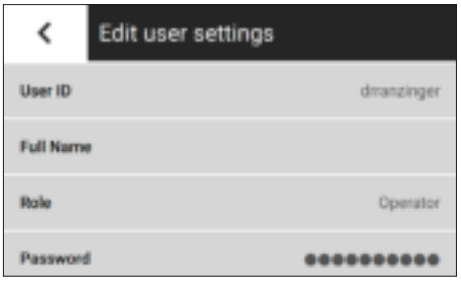
4.6.5 Update User

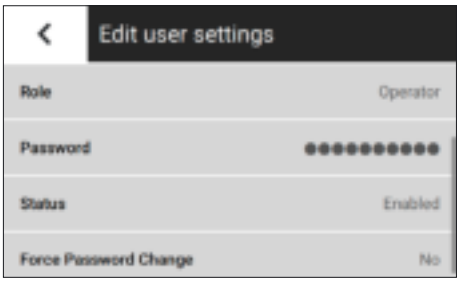
Users with role „Administrator“ can update an existing user account.

Procedure

▶ Select the user account to be updated.

▶ Press button [Edit] (1).





Change the following properties of an user account:

Property	Description
Full Name	e.g. first name and surname
Role	Operator | Administrator
Password	The password for authenticating the user.
Status	Enabled: The user can log in with the account. Disabled: The user cannot log in with the account.
Force Password Change	Yes: The user is forced to change the account’s password when logging in next time.

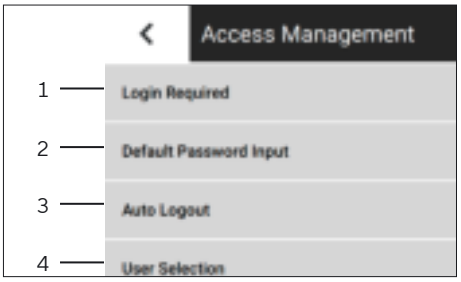
4.7 Access Management

The access management can be used to switch on | off the necessity to be logged in in order to use to device for welding. It also controls the device's behavior regarding the log in process.

Procedure

▶ Press button [Menu] (1) on the home screen.

▶ Press button [Access Management].

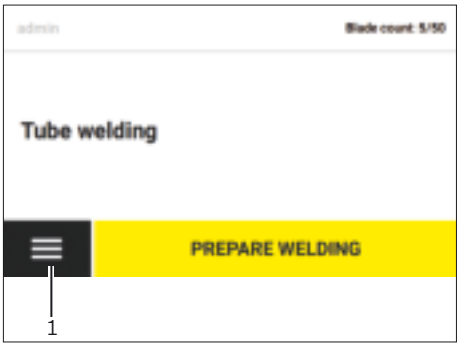


▶ Choose between the following categories:

Pos.	Category
1	Login Required
2	Default Password Input
3	Auto Logout
4	User Selection
5	Local User Management (not shown)

4.8 Device Settings

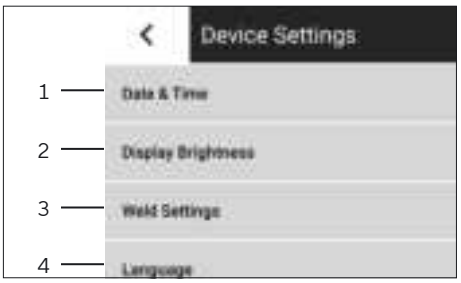
Procedure

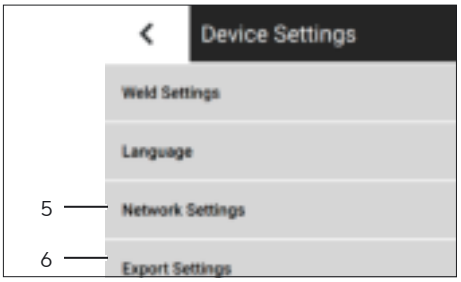


▶ Press button [Menu] (1) on the home screen.

▶ Press button [Device Settings].

▶ Choose between the following categories:





Pos.	Category
1	Date & Time
2	Display Brightness
3	Weld Settings
4	Language
5	Network Settings
6	Export Settings

5 Installation

5.1 Scope of Delivery

Article	Quantity
Biowelder® S	1
Tray Support	2
Cover inserts	2
Trays	2
Power Cord (supplied separately)	1
Torque screwdriver (4.2 Nm)	1
Hexagon Bit 4 mm	1
Operating Instructions	1

NOTICE The country-specific Power Cord is not included in the packaging of the device and is supplied separately.
The Blade Cartridge (article number: BWSBC0010) is not included in the packaging of the device and must be ordered separately.

5.2 Selecting an Installation Site

Procedure

▶ Ensure that the installation conditions have been met (see Chapter “15.2 Installation | Transport Conditions”, page 45).

5.3 Unpacking

Procedure

▶ Open the package.
▶ Remove the top layer of foam packaging.
▷ The device has recessed grips for carrying the device on the lower left and lower right sides.
▶ Lift the device out of the packaging using the recessed grips.

▶ Sartorius recommends keeping the original packaging to return the device appropriately, e.g., for repairs and maintenance.

5.4 Acclimatization

When a cold device is brought into a warm environment: The temperature difference can lead to condensation from humidity in the device (moisture formation). Moisture in the device can lead to malfunctions.

Procedure

- ▶ Allow the device to acclimatize to the installation site. The device must be disconnected from the power supply during that time.

5.5 Installing Trays

The device is supplied with 2 cover inserts, which are already installed.

Procedure

- ▶ **NOTICE** Risk of damage to the device if the maximum permitted weights for the tray supports are exceeded.
  - ▷ The maximum load is 5 kg per tray support.
- ▶ Slide the existing cover inserts out of the device.
- ▶ Place the trays in the appropriate position.

5.6 Installing the Blade Cartridge

Procedure

- ▶ Open the blade cartridge drawer. This can be found on the front of the device (1).
- ▶ Position the blade cartridge in the drawer.
- ▶ **NOTICE** Risk of contamination and | or unclean welding!
  - ▶ If the cartridge falls down or is contaminated at anytime, do not use the cartridge anymore!
  - ▶ Do not touch the blades at any time of the process!
- ▶ Close the blade cartridge drawer.
- ▶ **NOTICE** The blade cartridge might touch the cover plate during insertion. This is on purpose as it ensures a proper alignment.

6 Commissioning

6.1 Connecting the Power Supply

Procedure

- ▶ Check whether the country-specific power plug matches the power supplies at the installation site.
  - ▶ If required: Order new cord as spare part.
  - ▶ If required: Contact Sartorius Service.
- ▶ Connect the device to the power supply.

6.2 Commissioning

Procedure

- ▶ Switch on the main supply switch.
- ▶ Wait until the start screen appears.

7 Process Preparation

⚠ CAUTION

Risk of infection with biohazardous material!

▶ Wear protective gloves during the entire preparation process!

7.1 Login

By default, the device can be used for cutting and welding tubes without operators having to log in. The necessity to be logged in can be turned on by a user with role „Administrator“ in the Access Management.

7.2 Clean tubes

▶ Use only clean tubes.
▶ If it is necessary to clean the tubes, contact the manufacturer of the tubes for information on permissible cleaning agents.

7.3 Prepare welding process

Procedure

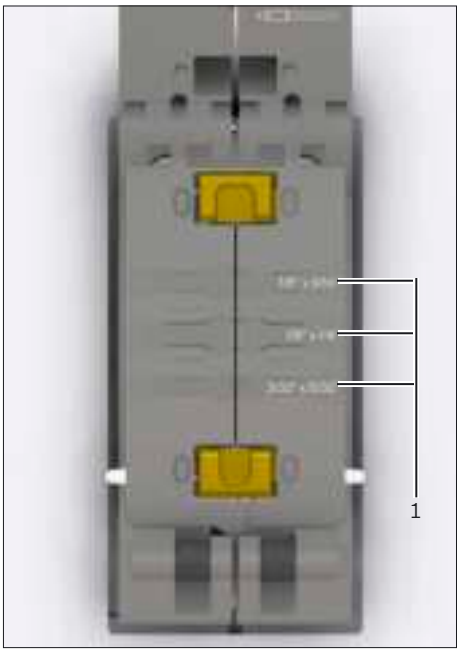
▶ The first prepare welding after system startup includes a very short device initialization. Remove the Biowelder® S Cartridge for this step.
▶ The device guides you step-by-step through inserting the tubing.
▶ **NOTICE** Before pressing the [PREPARE WELDING] button, make sure that no tube is placed in the tube holder. Otherwise the tube could be unnecessarily stressed by the initialization of the tube holder.
▶ Press button [PREPARE WELDING] (1).
▷ **NOTICE** By default, the device does not ask the operator to specify the tube type before welding. The option to specify the tube type welded can be turned on by a user with role „Administrator“ in the Weld Settings.

▶ Confirm or change tube type.
▶ To continue the welding process, press [CONTINUE].
▶ To change the tube type, press [CHANGE]:

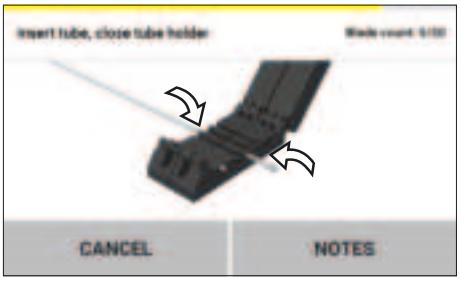
- Select the tube material [PVC] or [TPE] and the size.
  - Choose between size [3/32 x 5/32], [1/8 x 3/16] or [1/8 x 1/4].
  - **NOTICE** Only two tubes of the same size and same material (PVC-PVC or TPE-TPE) can be welded together.

- Press button [NOTES] for entering pre-weld notes.
- Open the tube holder (1).

- Open the middle layer (1).



- Insert the first | lower tube into the appropriate slot in the tube holder according to its size (1).
- Use a minimum of 200 mm free tubing, if filled. Use a minimum of 100 mm if dry or wet.
- ⚠ **CAUTION** Risk of deflagration due to flammable vaporisation! Ensure that there are no residues of evaporation on the tubes.
- **NOTICE** The left side of the lower tubing will be connected to the right side with the upper tubing.



- ▶ **NOTICE** Carefully press the tube into the slot in the tube holder until the tube is completely in the position provided.

- ▶ Close the middle layer.
- ▶ Insert the second | upper tube into the appropriate slot in the tube holder according to the size of the first tube.
- ▶ Close the tube holder.
- ▶ **NOTICE** For reasons of safety, seal off the tubes on all sides with a clamp, plug or another seal before every welding.
  - ▶ Attach the clamps at a distance between 5 and 20 cm to the tube holder (in case of filled tubing) or 3 to 20 cm (in case of dry or wet tubing).

- ▶ Use a valid blade cartridge container with at least one blade.

8 Operation

8.1 Welding process

⚠ CAUTION

Risk of infection from biohazardous material!

▶ Wear protective gloves during the entire welding process!

NOTICE

The device uses RFID technology to exchange data with the blade cartridge at an operation frequency at 13.56 MHz.

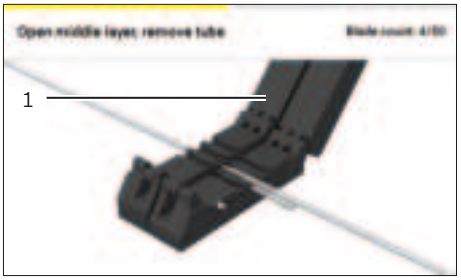
Requirements

– Tubes are inserted into the tube holder.
– The middle layer and the tube holder are properly closed.
– There is a valid blade cartridge in the blade cartridge drawer.
– The blade cartridge drawer is properly closed.
– The blade cartridge must contain at least 1 blade.

Procedure

▶ **⚠ CAUTION** Danger of burns due to hot surfaces! Do not touch the blade before and after welding.
▶ **⚠ CAUTION** Risk of infection from biohazardous material! Do not touch the blade before and after welding.
▶ **NOTICE** It is recommended to clamp both tubes on both sides. In case of dry or wet tubes, the distance should be approx. 100 mm. In case of liquid filled tubes the distance should be approx. 200 mm. Ensure to weld the central part between the clamps.
▶ Slide the controller (1) to the right to start the welding process.

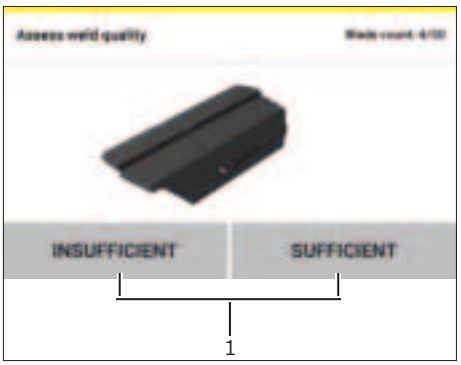
▶ **NOTICE** Opening the blade cartridge drawer and the tube holder during the welding process can cause damage to the device. The tube holder and the blade cartridge drawer are locked during the welding process. Do not open the tube holder or the blade cartridge drawer.
▶ **NOTICE** No tension or stress shall be applied on tubing during the entire welding process.
▶ Once the welding process has been completed, follow the step-by-step instructions on the display to remove the pieces of tubing.
▶ Open the tube holder.
▶ Remove the upper discarded end of tubing.
▶ Lift the left middle layer (1) to be able to remove the welded tubing.



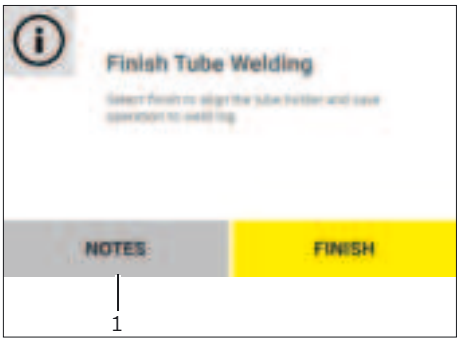
- ▶ If the welded tubing is still blocked at the location of weld, please gently push perpendicular to the weld in order to unblock the welded tubing.
- ▶ Visually check the tubing connection after every welding operation.

- ▶ Lift the right middle layer and remove the lower discarded end of tubing.
- ▶ ⚠ **CAUTION** Risk of infection from biohazardous material!
  - ▶ Only touch the tube waste with protective gloves.
  - ▶ Dispose the discarded ends of the tubes immediately after the welding to prevent any risk of contamination.
- ▶ Close the middle layer and the tube holder (1).
  - ▶ Make sure that all tubes and tube remnants have been removed from the tube holder.

- ▶ **NOTICE** If no error message is shown, the welding operation was performed according to preset parameters.
- ▶ Press the button [INSUFFICIENT] or [SUFFICIENT] to assess the welding quality (1).
- ▷ **NOTICE** By default, the device does not prompt the operator to assess the quality of the weld. The option to asses the weld quality can be turned on by a user with role „Administrator“ in the Weld Settings.



- ▶ If the welding quality was [INSUFFICIENT], select a reason for a bad assessment.
- ▶ If the welding quality was [SUFFICIENT], press button [NOTES] for entering post-weld notes (1).



- ▶ Press button [FINISH].
  - ▷ During this process, the vertical shift of the tube holder is reset and the used blade is ejected into the container for used blades.

8.2 Switch off the device

Procedure

- ▶ Switch off the main supply switch on the back of the device.

9 Cleaning and Maintenance

9.1 Cleaning

⚠ WARNING

Risk of injury due to voltage!

Dangerous voltage if the device comes into contact with liquids!

- ▶ Switch off the device and disconnect it from the power supply.
- ▶ Do not sterilize either the device or the tube holder in a sterilization system.
- ▶ Do not immerse the device in liquid solutions.

Requirements

The process has been completed.

Procedure

- ▶ Only use suitable cleaning agents and observe the product information for the cleaning agent used.
- ▶ Wipe the housing with a slightly damp cloth. In the case of more heavy contamination, use a mild soapy solution or a suitable cleaning agent (see Chapter "15.6 Cleaning Agent and Cleaning Method Device", page 47).
- ▶ Do not use a cleaning agent with solvents!
- ▶ **NOTICE** Sharp-edged objects may damage the device! Do not place any sharp or metallic objects on the device or between the open tube holder layers!
- ▶ Wipe the tube holder with a slightly damp cloth
  - ▶ In the case of more heavy contamination see Chapter "9.2 Cleaning the tube holder", page 36.

9.2 Cleaning the tube holder

Qualification required: Administrator

Requirements

The process has been completed.

Procedure

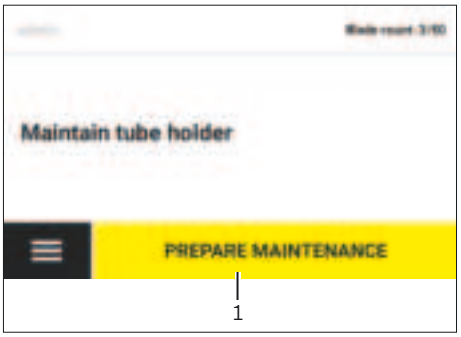
- ▶ **NOTICE** If the tube holder is not removed properly, this may damage the device. Do not remove the tube holder before the device has been put in the intended state. Do not switch on the device and | or connect the device if the tube holder is dismounted.
- ▶ A suitable password must be created for the administrator to be able to remove the tube holder. The password is provided during the course of the product training.

9.2.1 Removing the Tube Holder

Material: Hexagon screwdriver

Procedure

- ▶ Install the device and carry out commissioning.
- ▶ Log in as an administrator with the password provided.
- ▶ Enter the Settings menu.
- ▶ Select [DEVICE MAINTENANCE].
- ▶ Select [MAINTAIN TUBE HOLDER].
- ▶ Select [PREPARE MAINTENANCE] (1).



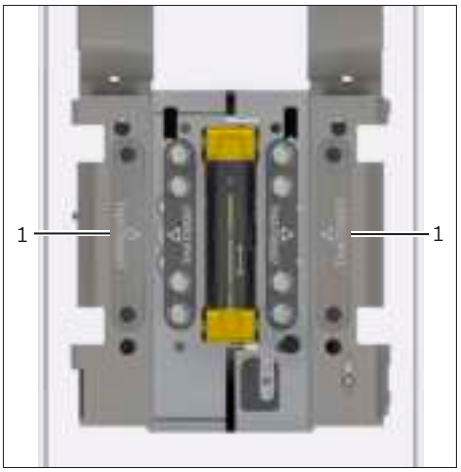
- ▶ Switch off the main power switch. Unplug the power cord.
- ▶ ⚠ **WARNING** Risk of lethal electrical shock when device is connected to a power supply! The power cord must be unplugged from the device and the device switched off while the tube holder is removed.
- ▶ Carefully dismount the tube holder using the hexagon screwdriver supplied.

- ▷ The tube holder can be cleaned.
- ▶ ⚠ **WARNING** Do not use any cleaning solutions for parts inside the device.
- ▶ **NOTICE** If work is performed incorrectly, this may damage device parts! Do not touch any parts that are inside the device and are accessible when the tube holder is removed.

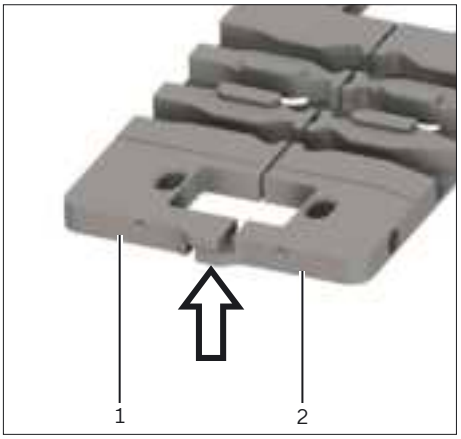
9.2.2 Installing the Tube Holder

Material: Hexagon screwdriver

Procedure



▶ **NOTICE** If the tube holder is assembled incorrectly, this may damage the device! When reinstalling the tube holder, check that the serial number on the tube holder matches the serial number on the device alignment blocks (1).



▶ Mount the tube holder using the hexagon screwdriver:
  ▶ The screws for the handle lock and the left (1) and right (2) middle layer must be mounted in the right order.
  ▶ Mount the screws including the washers.

  ▶ Ensure that the interlock (3) between the right and left handle is intact.
  ▶ First, loosely tighten all four screws.
  ▶ Then tighten all four screws using the hexagon screwdriver until torque of 4.2 Nm is reached.
▶ Connect the power cord, switch on the device, and commission it.

9.3 Replacing Fuses

Qualification required: Electrician

Procedure

- ▶ Unplug the power cord.
- ▶ Remove the fuse drawer from back of the device using a flat screwdriver.
- ▶ Only replace fuses with fuses of the same type and value (see Chapter "15.4.1 Power Supply Unit", page 46).
- ▶ Slide the fuse drawer back into the housing.
- ▶ Press the fuse drawer in until you hear a click. This confirms that it is in the correct position.
- ▶ Connect the power cord to the device's power inlet.

9.4 Service Cycles

To ensure reliable operation, the device must be checked regularly by Sartorius Service. The necessity of an inspection depends on how long it has been since the last inspection and how many welding processes have been carried out. The device issues a regular warning message 45 days or 3000 welds before the next inspection is due, reminding the user to schedule an inspection appointment.

10 Faults

10.1 Error Messages

- ▶ The device must be reinitialized after every error message.
- ▶ Follow the device's instructions for this.
- ▶ If the problem persists, contact Sartorius Service.

Error message	Cause	Solution
Error: rxxsyy	Various	▶ Restart the device. ▶ Remove the blade cartridge. ▶ Empty the container for used blades. ▶ Initialize the device. ▶ If initialization was successful, reinsert the blade cartridge.
The device requests initialization to be carried out after each reset phase.	The blades are not falling into the blade container correctly.	▶ Contact Sartorius Service.
Machine failure	Internal electrical defect.	▶ Restart the device.

10.2 Problems during Operation

Issue	Cause	Solution
The device does not start.	The power supply cable	▶ Check the power supply circuit breaker. ▶ Check the circuit breaker of the power supply.
	The fuse is defective.	▶ Check the fuse on the rear of the device.
The tube holder cannot be opened.	The unlocking operation has failed.	▶ Restart and initialize the device.
The used blade container cannot be opened.	The welding operation is not yet complete.	▶ A blade may not have been ejected properly and is blocking the opening of the drawer. ▶ Gently shaking the used blade container can force the blade to drop correctly.
		▶ Conclude the cycle that is in progress. ▶ Remove the tubing and reset the tube holder. ▶ If that is not possible, restart the device.

Issue	Cause	Solution
Touchscreen is no longer working | Display freezes	Electrical overload	▶ Restart the device twice (2x) and remove the tubes before re-initializing.
Missing “Welding finished” entry in the Log-File		▶ No action required.
Discrepancy between available blade in the cartridge and real amount of available blade(s)	Electrical overload	▶ The device will display an error and end the welding process. The device will request then to be re-initialized.

11 Decommissioning

11.1 Decommissioning the Device

Requirements

The process is finished.

Procedure

- ▶ Switch off the device.
- ▶ Disconnect the device from the power supply and all supply systems. To do so, remove all cables and tubing.
- ▶ Remove the blade cartridge.
- ▶ Empty the container for used blades.
- ▶ Clean the device.

11.2 Dismounting Trays

Procedure

- ▶ Slide the existing trays out of the device.
- ▶ Reinstall the cover inserts.

12 Transport

Requirements

- – The device has been decommissioned.
- – The trays are dismounted.
- – The cover inserts are mounted.

Procedure

- ▶ ⚠ **CAUTION** Risk of injury when lifting or transporting!
  - ▶ Disconnect the device from all connections at the installation site.
  - ▶ Use both hands when transporting the device and setting it down. To do this, reach sideways under the device with both hands.
- ▶ Use a trolley for longer transport routes.

13 Storage and Shipping

13.1 Storing

Requirements

The device has been decommissioned.

Procedure

- ▶ Store the device according to the ambient conditions (see Chapter "15.2 Installation | Transport Conditions", page 45).
- ▶ Do not stack the devices. Store it in the original package.

13.2 Returning the Device and Parts

Defective devices or parts can be returned to Sartorius. Returned devices must be clean and packed in their original packaging.

Transport damage as well as measures for subsequent cleaning and disinfection of the device or parts by Sartorius are charged to the sender.

Devices contaminated with hazardous materials, e.g., harmful biological or chemical substances, will **not** be accepted for repair or disposal.

Procedure

- ▶ Decommission the device.
- ▶ Contact Sartorius Service for instructions on how to return devices or parts (please refer to www.sartorius.com).
- ▶ Pack the device and its parts in their original packaging for return.

14 Disposal

14.1 Decontaminating the Device

The device does not contain any hazardous materials that necessitate special disposal measures.

The cultures and media (e.g., acids and bases) used during the process are potentially hazardous substances that can cause biological or chemical hazards.

If the device has come into contact with hazardous substances, steps must be taken to ensure proper decontamination and declaration.

Procedure

- ▶ Decontaminate the device. The company operating the device is responsible for adhering to local government regulations on the proper decontamination and declaration for transport and disposal.
- ▶ **NOTICE** The container for used blades may be filled with used blades. Clean and decontaminate the waste container carefully.

14.2 Disposing of the Device and Parts

The device and the device accessories must be disposed of properly by disposal facilities.

One lithium cell battery is installed inside the device. Batteries must be disposed of properly by disposal facilities.

Requirements

- The device has been decommissioned.
- The device has been decontaminated.

Procedure

- ▶ Please contact Sartorius Service. The device must be dismantled by Sartorius Service.
- ▶ Dispose of the device in accordance with local government regulations. Inform the disposal facility that there is one lithium cell battery installed inside the device.
- ▶ Dispose of the packaging in accordance with local government regulations.

15 Technical Data

15.1 Dimensions and Weight

	Unit	Value
Without tray holder		
Length x width x height	cm	27 x 41 x 23
Weight	kg	14.3
With tray holder		
Length x width x height	cm	59 x 41 x 23
Weight	kg	15.2

15.2 Installation | Transport Conditions

	Unit	Value
The installation site meets the requirements relating to the operating conditions.		
Access to operation-relevant parts is guaranteed.		
Space Requirements		
Suitable for the dimensions of the device and the associated components		
Setup Surface		
Suitable for the weight of the device and the associated components.		
Stable, fully flat, even		
Installation site		
Standard laboratory rooms		
For indoor use only		
Maximum altitude above sea level	m	2000

15.3 Operating Conditions

	Unit	Value
Relative air humidity — up to 31°C, decreasing linearly to 50 % at 40°C, non-condensing	%	20 – 80
Storage temperature	°C	-10 – +60
Pressure	hPa	500 – 1060
Operating temperature	°C	+20 – +32.2
	°F	68 - 90
Operating angle, max.	°	5
The device is a class A product. In a domestic environment this product may cause radio interference (emission).		

15.4 Electrical Data

15.4.1 Power Supply Unit

	Unit	Value
AC voltage	V	100 – 240
Frequency	Hz	50 – 60
Current consumption, maximum	A	2.8
Power consumption, maximum	W	280
Short circuit protection: Electronic		
Fuses of the device		
Number		2
Type	V	250
Rate	A	3.15 T
Protection class according to IEC 61010-1		IP
Pollution level according to IEC 60529-1		2x

15.4.2 In and Out Connections

	Unit	Value
USB		2.0
		cable type A with shielding
XLR Connector, max.	V	24
	A	2
Ethernet		

15.4.3 Fume Extraction Connector

	Unit	Value
Diameter	mm	53
	"	2
External air filter system, maximum	m^3/hr	20
	L/min	5

15.5 Tube Specifications

	Value
Material	Polyvinyl chloride (PVC) Thermoplastic elastomer (TPE)
Inner diameter x outer diameter	3/32" x 5/32" 1/8" x 3/16" 1/8" x 1/4"

15.6 Cleaning Agent and Cleaning Method Device

Approved cleaning agents device
Propanol 45 %, Isopropanol 25 %, Ethanol 4.7 % (e.g. Bacillol AF)
Ethanol 70 % (e.g. Klercide 70|30)
Chlorine bleach solution or diluted chlorine bleach (e.g. Klercide-CR)
neutral cleaning agents
Approved cleaning method
Wiping the device surfaces with a slightly damp cleaning cloth
No autoclaving

16 Conformity Documents

The attached documents declare the conformity of the device with the designated directives or standards.

SARTORIUS

Original

CE

EG-/EU-Konformitätserklärung
EC / EU Declaration of Conformity

Hersteller / *Manufacturer*: **Sartorius Stedim Switzerland AG**
Ringstr. 24a, 8317 Tagelswangen, Schweiz/Switzerland

erklärt in alleiniger Verantwortung, dass das Betriebsmittel
declares under sole responsibility that the equipment

Gerätesart / *Device type*: Schlauchschweissgerät
Sterile Tube Welding Device

Baureihe / *Type series*: **Biowelder® S**

Modell / *Model*: **Biowelder S 1.0**

in der von uns in Verkehr gebrachten Ausführung allen einschlägigen Bestimmungen der folgenden Europäischen Richtlinien entspricht und die anwendbaren Anforderungen folgender harmonisierter Europäischer Normen einschließlich deren zum Zeitpunkt der Erklärung geltenden Änderungen erfüllt:
in the form as delivered fulfils all the relevant provisions of the following European Directives and meets the applicable requirements of the harmonized European Standards including any amendments valid at the time this declaration was signed listed below:

2014/30/EU	Elektromagnetische Verträglichkeit / *Electromagnetic compatibility* EN 61326-1:2013
2011/65/EU (EU) 2015/863	Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronik-geräten (RoHS) / *Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)* EN IEC 63000:2018
2006/42/EG 2006/42/EC	Maschinen *Machines* EN ISO 12100:2010, EN 61010-1:2010/A1:2019*
2014/53/EU	Funkanlagen / *Radio Equipment* ETSI EN 303 446-2, ETSI EN 301 489-3, ETSI EN 301 489-1

Die Person, die bevollmächtigt ist, die technischen Unterlagen zusammenzustellen:
The person authorized to compile the technical file:

Sartorius Stedim Switzerland AG
Ringstr. 24a, 8317 Tagelswangen,
Schweiz

Sartorius Stedim Switzerland AG
Tagelswangen, 2024-06-28

Christine Lettenbauer
Digital unterschrieben von Christine Lettenbauer
Datum: 2024.06.28 12:58:03 +02'00'

Digitally signed by Katrin Schulze
Date: 2024.07.03 14:04:37 +02'00'

Christine Lettenbauer
Geschäftsführerin CE

Katrin Schulze
Quality System Manager

*: angewandte, jedoch für Maschinen nicht harmonisierte Norm /
applied standard, which however is not harmonized for machines

Doc: 3355120-00 SST24CED01-00.de,en 1 / 1 PMF: 3357331 OP-113_fo1_2020.07.07.docx

Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen, Germany

Phone: +49 551 308 0
www.sartorius.com

The information and figures contained in these instructions correspond to the version date specified below.
Sartorius reserves the right to make changes to the technology, features, specifications and design of the equipment without notice.
Masculine or feminine forms are used to facilitate legibility in these instructions and always simultaneously denote all genders.

Copyright notice:
These instructions, including all components, are protected by copyright.
Any use beyond the limits of the copyright law is not permitted without our approval.
This applies in particular to reprinting, translation and editing irrespective of the type of media used.

Last updated:

08 | 2024

℗ 2024
Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen, Germany

KS | Publication No.: SPG6059-e240801